86. Instead of testing the critical hypothesized relationship between expectations and reimbursement rates, Dr. Hartman simply assumes his conclusion that reimbursement rates would change with changes in expectations when he rejects direct evidence about expectations as unreliable unless it leads to changes in reimbursement rates:[83]

> Dr. Hartman:
>
> When I see (payors) start to say, look, we want to reimburse on acquisition cost and there is a definition of what that means, that will say to me that they...are now revealing an understanding of the fact that these spreads are well above what the – what we thought they were.[84]

87. In summary, Dr. Hartman offers no evidence that the class members had expectations about spreads that informed their reimbursement rates, and if they did, no evidence of what any expectations were. He does not offer any evidence that whatever expectations of spreads

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[83] See also Hartman Deposition at 823:6-16: "As a matter for an economist, one finds that preferences and expectations are revealed when behavior is exhibited, and when there is a shift in the way reimbursement is paid or contractually the way – what kinds of discounts are offered off of AWP or whether it is related to ASP. That then shows that there has been enough information that they have come to an understanding that is sufficient to make them move to avoid the problems that are slowly becoming clear to them."

Dr. Hartman testifies about the fact that BCBSMA, a class representative in this case, continues to reimburse PADs at 95% of AWP: "[T]his doesn't contradict anything that has been put forward here. They have yet to reveal how they are going to respond when they commit to changing the - a system that has been put in place based on older expectations that have since been violated." (Hartman Deposition at 841:11-15)

Dr. Hartman explained that: "[W]hen third-party payors say we're reimbursing on ASP or AWP less 70 percent, that will reveal to me that enough of this information has been reflected in – in their behavior." (Hartman Deposition at 985:8-11).

Similarly, Dr. Hartman testified: "Q: Evidence that (spread competition for multi-source PADs) was common knowledge would be of interest to you, correct? A: Evidence that reimbursements should change as a result of the fact that – that the – the patterns that have been put in place should be altered to eliminate the amounts of money that were being made, that should be changed, that would be of interest to me." (Hartman Deposition at 1003:13-20).

[84] Hartman Deposition at 788:17-789:1.

that may have existed fell into a relatively narrow range that never exceeds 30%.[85] Because AWPs are transparent to payors and competition was known and would be expected to reduce ASPs, it would be reasonable as a matter of economic logic to expect that spreads for drugs facing competition exceeded those for single-source innovator drugs.[86] Indeed, to the extent that the data and documents used by Dr. Hartman to estimate his yardsticks reflected or informed payor expectations, they indicate that payors would expect that spreads for drugs facing therapeutic or generic competition would exceed spreads for drugs that did not face such competition.[87]

VI. DR. HARTMAN'S DAMAGES ANALYSIS: WHAT WOULD AWP, ASP, AND REIMBURSEMENT RATES BE IN THE ABSENCE OF THE ALLEGED FRAUD?

88. Recall that the fundamental premise of Dr. Hartman's liability analysis is that pharmaceutical companies increased spreads to increase sales volumes and that payors were ignorant of these spreads. Dr. Hartman articulated the view that had payors known about the spreads, they would have adjusted reimbursement rates in response to capture for themselves the discounts from list price offered to physicians exceeding the 30% "yardstick."[88]

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[85] Indeed, Dr. Hartman testified that "I cannot make the statement that no one, no payer, knew that there weren't mega-spreads. I, you know, I don't know whether they did or they didn't." (Hartman Deposition at 796:6-10).

[86] Plaintiffs' expert Dr. Rosenthal has acknowledged that therapeutic competition would be expected to result in discounting and increased spreads. For example, she testified: "I do think the amount of therapeutic competition in terms of the effects of the drugs and side effects would be a factor in that kind of discounting." (Rosenthal Deposition, February 22, 2006 at 87:11-14).

[87] The finding in the studies cited by Dr. Hartman that spreads did in fact exceed 30% for some drugs was also reflected in a 1996 *Barron's* article that stated that "For many drugs, especially the growing number coming off patent and going generic, the drug providers actually pay wholesale prices that are 60-90% below the so-called average wholesale price..." A discount of 90% results is a spread of 1000%. A table accompanying the articles showed drugs with even higher spreads. See Alpert, B., "Hooked on Drugs," *Barron's*, June 1996, pp. 15-18.

[88] For example, Hartman Declaration, December 15, 2005, pp. 9-10.

89. It might be expected that to determine his but-for world, Dr. Hartman would estimate what reimbursement rates would have been for each payor had they known the increased spreads. Dr. Hartman makes no such analysis. Instead, his model assumes that reimbursement rates outside of Medicare and selling prices to physicians would be unchanged. He assumes that the pharmaceutical companies would have changed their reported AWP in order to maintain the same relationship to ASP for drugs that faced therapeutic or generic competition as for those that did not. For Medicare damages, Dr. Hartman applies a different but-for AWP than for non-Medicare claims, which is of course impossible. But he appears to do so as a computational short-hand to implement his legal interpretation of reimbursement required by statue.

A. Non-Medicare Payors

90. Dr. Hartman applies one formula to calculate damages for all class members, all drug categories, and at all times during the damage period for non-Medicare claims. Damages are based on the product of the reimbursement rate and the calculated gap between the actual AWP and the but-for AWP, (*i.e.*, the AWP that would have been observed but for the alleged fraud):

(1) Damages for non-Medicare = contract reimbursement rate * (As-is Spread – But-for Spread) * ASP * Quantity

91. Note that the *only* variable that is different between the but-for and the as-is worlds in Dr. Hartman's damages formula is the AWP – all other variables retain the same values. The but-for AWPs for each NDC are estimated by reference to actual ASPs and incorporate the maximum spread that Dr. Hartman assumes payors would expect across all drugs (30%).[89] The reimbursement rate, *which is the mechanism by which Dr. Hartman argued payors*

[89] Although Dr. Hartman testified that the relevant ASP was the ASP paid by physician-providers, his supplemental report calculates a lower ASP (thereby increasing damages) based on all transactions, including for example more heavily discounted sales to hospitals. (See, for example, Hartman Deposition at 658:11-661:13).

would adjust to information about spreads (and therefore the variable that would change in the but-for world), is unchanged.[90]

92. There are two alternative interpretations of Dr. Hartman's approach to damages. The first and most direct is that he indeed expects that absent the fraud, pharmaceutical companies would have adjusted their AWPs downward as he assumes and all other variables would remain unchanged. I show that this result simply will not occur if the drug companies are free to set spreads as competitive conditions warrant and can cure the alleged fraud by correcting plaintiffs' allegedly misinformed expectations. This is because pharmaceutical companies will face the same basic economic incentives to increase spreads to compete regardless of whether payors are informed about the spreads.

93. The only way that Dr. Hartman's but-for spreads would exist for drugs facing competition is if they were mandated legally. In that scenario, liability for fraud and damages now arises *per se* from price competition to "move market share," irrespective of plaintiff expectations in the real world – there is no longer any causal link between expectations and the alleged fraud. Even under that scenario, Dr. Hartman's conclusions are incorrect. AWP and ASP will not drop as Dr. Hartman predicts in the face of new competition, and indeed AWP and ASP would likely be *higher* as a result of the incentives that would face drug companies and physicians if spreads were constrained legally not to exceed 30%.

94. Finally, I consider and dismiss the possibility that Dr. Hartman's model might correctly estimate the quantum of damages that would arise not through changes in but-for AWP, but

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[90] Recall that a critical assumption of Dr. Hartman's liability theory is that reimbursement rates would be different in the but-for world where payors know of the alleged inflated spreads. See Hartman Declaration, December 15, 2005, pp. 9-10:

> Dr. Hartman
> The negotiation also relies upon an anticipation that the AWP provides a signal for the underlying spreads. Had the existence of the "mega-spreads" been perceived and understood by TPPs, those payers would have negotiated more aggressively than they did, leading to lower reimbursement rates. (Footnote omitted)

through changes in reimbursement rates. In this alternative, Dr. Hartman would not mean his formulaic approach to be interpreted as written. Rather he would believe that reimbursement rates would in fact adjust to capture fully the difference between the as-is and the but-for spreads. That is, his formula is a simpler way of estimating the quantum of damages rather than reflecting also what the fraud-free world looks like. I show that this too is incorrect.

I. Would AWP Drop and ASP Remain Unchanged as Dr. Hartman Predicts if Payors Were Informed?

95. Dr. Hartman's model appears to assume that fraud is defined as spreads that were unknown to payors, but companies are free otherwise to set their prices and to compete. Then it is necessary to ask whether competition would drive drug companies in the fraud-free world to keep ASPs at the same levels as they did in the as-is world. If so, we must also ask whether it would drive them also to have dropped AWPs to maintain a spread of not more than 30%.

96. To begin, note that if the fraud is defined in terms of expectations, then it can be cured by informing the expectations rather than by conforming spreads to some defined limit. For example, drug companies could announce that published AWP bears no "reasonably predictable" relationship to ASP.[91] If required, drug companies might publish more information about specific spreads. Even in this case, however, increasing spreads to physicians would remain an effective way for drug manufacturers to compete in the Hartman damage methodology.

97. The intuition is straightforward. If the alleged fraud is cured by changing alleged payor expectations, drug companies would continue to compete by increasing spreads to gain market share as competition increases.

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[91] At least one manufacturer, Schering Corporation, has provided such a disclosure. See SP Ex. 40 (WAR 0065610), an April 2003 price list provided to the Connecticut Commission that states "[t]he AWP shown is not an average of wholesale prices, nor does it reflect the price of any wholesale transaction."

98. The incentive to change spreads to attract volume does not arise from the alleged hidden nature of the spreads from the point of view of payors. It arises because cutting price and increasing spreads make drugs more attractive economically to the physicians that prescribe them.[92] Thus even if payors knew that there was no predictable relationship between AWP and ASP for all drugs, and even if spreads or ASPs were published, competition for sales to physicians would continue to create pressure to increase spreads. This is in fact the normal competitive process of firms cutting prices in response to competition in order to gain a temporary market share advantage.[93]

99. It should be clear, therefore, that the but-for world in Dr. Hartman's model, where reimbursement rates and ASPs and reimbursement rates do not change but AWP drops to keep spreads under 30, cannot be taken literally as he presents it. If fraud depends on expectations, the expected competitive result would be to provide whatever minimum information cures the fraud, rather than to cut AWP so that spreads are no more for drugs facing competition than they are for drugs that do not. That is, even in the fraud-free world, pharmaceutical companies will continue to face competitive pressure to increase spreads. Dr. Hartman's analysis therefore requires that fraud is independent of expectations. That is, the definition of fraud presented in his initial report and reiterated in his damage report must now be changed to a *per se* theory to support his damage calculations. Alternatively, to be consistent with his liability theory, he must argue that AWP would not drop as his formula asserts, but rather that reimbursement rates would adjust so that an economically equivalent result is obtained by payors.

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[92] In some cases, spreads may be increased by raising AWP. However, this would not be secret, as explained above. I note that raising the list price while providing discounts to some customers would be expected where there exists a price-insensitive segment of customers paying list prices and a more price sensitive segment that negotiates for discounts.

[93] Note that even informed expectations are not instantaneously informed, so that there remains an incentive to cut price to increase volume even if the prices subsequently become public. I discuss below why instantaneous information generally undermines the normal competitive process by eliminating the motivation for the supplier to cut prices in the first place.

2. *Would AWP Drop as Dr. Hartman Predicts and ASP Remain Unchanged if Drug Companies Were Confined to a Regulated Spread?*

100. Above I showed that the only way for Dr. Hartman's damage formula to hold as it is presented (see equation (1) above) would be to define spreads above a certain level as *per se* illegal. In this case there would be no causal connection between 1) Dr. Hartman's damages calculations and 2) any alleged discrepancy between actual and expected spreads.[94] Fraud would arise not because spreads were higher than payors expected, but rather simply because spreads exceed 30%, regardless of what spread payors expected.[95]

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[94] This offering of an entirely different causal connection between liability theory and damages that is divorced entirely from expectations in the actual world is clear when:

i. Dr. Hartman argues that even though some plaintiffs may have had no expectations of spread in the real world and did not rely on them to negotiate contracts, they must nevertheless have been harmed by fraud: "*Even if a Class member did not care about the relevant distributor's acquisition costs, that Class member was still injured and overcharged by the extent to which the AWP was artificially inflated above the but-for AWP*, since the reimbursement rates paid by that class member were formulaically referenced to those AWPs and were therefore subject to an overcharge." (Hartman Deposition, December 16, 2004, p. 21. Emphasis added).

This result occurs in fact in the damage model because it calculates damages regardless of expectations based on the "spread gap" created by assuming that there is no generic or therapeutic competition in the but-for world;

ii. He argues that "comparator drugs" used to calculate but-for spreads should be those not facing generic or therapeutic competition, because "a given manufacturer would find it unnecessary and unprofitable to increase spreads to move market share" if it were not for competition (Hartman Declaration, December 15, 2005, pp. 15-16. Emphasis in original);

iii. He claims that evidence of spreads greater than 30 percent support the conclusion that ". . . the manufacturer has fraudulently increased the spread on that NDC in that period to move market share" (Hartman Declaration December 15, 2005, p. 40); and

iv. He cites the report of Professor Rosenthal on liability, who concludes that "I concluded in my report that the class was harmed because these incentives [of manufacturers to compete with spread] were present." See Rosenthal Deposition at 377:19-20.

[95] See Hartman Deposition at 938:2-5:

Q. So, the basis for any opinion on liability you may give is simply a comparison of actual spreads with yardstick spreads, correct?
A. That's correct.

101. This *per se* description of fraud is in fact the only logical way to interpret the yardsticks selected by Dr. Hartman. Specifically, the yardsticks attempt to identify what spreads would be absent competition rather than what expectations of the class members actually were in the as-is world and how they affected reimbursement rates. Damages now arise whenever defendants act to "move market share," irrespective of payor expectations or contracting behavior:

> Dr. Hartman:
>
> Specifically, if a manufacturer either raises its AWP and/or lowers its ASP such that the realized spread exceeds 30% for a given NDC for a given period of time (I choose a year), I conclude that the manufacturer has fraudulently increased the spread on that NDC in that period to move market share.[96]

102. Note that in describing fraud as he applies it in his liability and damages model, Dr. Hartman now uses the concept of "expectations" to refer not to the actual expectations of the class members, but rather to what expectations would be if drug companies never competed by increasing spreads and spreads were kept at levels consistent with those for drugs not facing competition.[97]

> Dr. Hartman:
>
> [S]uccessful 'break-through' innovator drugs serve as reasonable yardsticks for 'but-for' spreads, specifically, for spreads that would be anticipated in the market *in which spread manipulation was*

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[96] Hartman Declaration, December 15, 2005, p. 40.

[97] This definition of expectations explains why despite the fact that Dr. Hartman claimed in his rebuttal report that the fact that spreads for self-administered generic drugs were "well known and has been well-documented," he claims in his later report that "[t]here is no evidence that the yardsticks for TPP price expectations for multi-source physician-administered drugs were any different than those for single-source physician-administered drugs....As a result, I use the same yardstick for liability for all physician-administered drugs, whether single-source or multi-source." (Hartman Declaration, December 15, 2005, p.42). He cannot mean actual expectations in the as-is world but rather expectations of what spreads would be if companies could not use them to compete.

> *unnecessary to move market share* for single-source branded drugs reimbursed by Sub-Class 3.[98]

103. If this definition of fraud is accepted, the relevant question now becomes whether ASPs would drop to the levels actually observed in the world where competition based on spreads took place if drug companies were legally required by a *per se* rule to limit spreads to no more than 30%. The answer clearly is "no."

104. It should give immediate pause to consider that in this scenario, Dr. Hartman's damages calculation would require that companies that cut prices in order to increase volume ("to move market share") would nevertheless cut them to the same extent *even when price cuts would create no such incentive because spreads would be unchanged.*[99] As Dr. Hartman explained, " ... the only reason that you would lower your – the – your unit revenue, your average sale price would be to take advantage of being able to move market share."[100]

105. If spreads beyond the initial level set for single-source innovator drugs are deemed to be *per se* illegal, how would competition occur for physician-administered drugs where formulary control is not feasible?[101] Since volume cannot be changed by increasing spreads, what is the incentive to cut price as competition enters? There is none: regulation of spreads by defining price cutting "to move market share" as *per se* fraudulent if spreads exceed 30% in

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[98] Hartman Declaration, December 15, 2005, p. 16. Emphasis added.

[99] Cuts in ASPs that would otherwise cause spreads to exceed 30% would require an offsetting reduction in AWPs, thereby undercutting the incentive effect of the price cut on providers and the profit motive to drug manufacturers.

[100] Hartman Deposition at 1144:1-4.

[101] For example, Dr. Hartman argues that "[C]ritical review of a provider's choice of drug therapy and the price of the selected drug is most typically believed to be beyond the expertise of the TPP. The provider determines the drug being administered. The choice of drug is determined by the training of the provider and the provider's specific knowledge of the patient, the patient's clinical profile and the patient's medical needs. (Hartman Declaration, December 15, 2005, p. 41); and that "[n]ot only do TPPs feel medically inadequate to review physician/provider choice of therapy, TPPs correctly believe that such review is not cost-effective." (Hartman Declaration, December 15, 2005, p. 41).

fact will *reduce* price competition, because there is no incentive in this but-for world for drug companies to reduce ASPs from the monopoly level as competition enters.[102]

106. Note that *raising* both ASP and AWP while preserving the 30% margin required by the Hartman formula would *increase* prices on PADs to physicians and reimbursement rates to plaintiffs. However it would also *increase* spreads to health care providers in dollar terms (*i.e.*, 30% of a higher ASP). According to the liability theories of the Hartman analysis, physicians would have an incentive to choose the most expensive therapies to maximize the base on which the 30% spread is calculated. Thus competition may act to pressure AWP and ASP higher rather than lower with corresponding costs to TPPs.

107. In summary, if the firm is constrained by law or regulation from increasing spreads beyond 30%, *ASPs* will be higher than they actually were and AWP may be higher as well. This contradicts Dr. Hartman's position that the ASP will not change in the but-for world. TPPs may be *worse* off in this but-for world because their reimbursements can be *higher* when the spreads are constrained relative to the "as-in" scenario in which the firm is allowed to increase spreads. More generally, based on observation of regulated industries, it is reasonable to conclude that when spreads are capped, competition will occur in other dimensions, such as added advertising or added sales staff, that typically do not pass through as benefits to retail consumers.

108. Dr. Hartman's *per se* rule makes little sense as a public policy. In his model, increased spreads that are expected by payors are recovered from physicians in higher reimbursement discounts. Class members benefit from increased spreads when they bargain for better terms with providers in Dr. Hartman's model. If ignorance of spreads is the problem, a better policy from the point of view of payors is to eliminate the ignorance rather than to eliminate the incentive of manufacturers to cut ASP and replace it with an incentive to raise ASP. I

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[102] Note also that a drug company facing competition could not unilaterally implement Dr. Hartman's but-for world. The "first mover" disadvantage would make it unprofitable for the drug company to set lower AWPs, as physicians would have no incentive to buy their drugs and would instead choose to buy competitor drugs that offer higher spreads and hence higher profits, according to the Hartman theory.

note also that in the PAD market, a cap in spreads (if it actually constrained provider incentives as Dr. Hartman alleges) may at the margin lead to exit of some physicians, reducing patient access, which could potentially harm consumers.

109. Thus, Dr. Hartman's damages calculations are inconsistent both with his theory of fraud and with basic economic principles and are overstated.

3. Is the Hartman Formula Short Hand for Changes to Reimbursement Rates?

110. I have explained why it is not possible to believe that Dr. Hartman's damages formula represents the way that prices would evolve absent the alleged fraud. The damages model, therefore, cannot be seen as plausible on its explicit terms. The question arises, therefore, whether it is possible that the mechanism in the formula is incorrect (that is that ASP would remain unchanged but that AWP would drop to eliminate spreads greater than 30%), but the formula is short hand for an adjustment that would take place through changes in reimbursement rates? Again, the answer is "no."

111. A threshold question is whether in fact reimbursement rates are based on expectations of spreads. In many markets buyers focus on the price they pay rather than on the margin the seller earns. Where margins are important to a decision, buyers seek out that information. When buyers view the information as important, services arise to provide it. Payors have a large number of sophisticated buyers and consultants. Dr. Hartman, however, provides no data that the payors sought out information about spreads in order to inform their reimbursement rates or that data vendors saw a market opportunity and responded to it.

112. Dyckman & Associates, as cited by Dr. Hartman, conducted a survey in which they asked the TPPs to rank the factors which influence the changes in their fee structure. Expectations about spreads was not cited as important in the responses. The three most important reasons given by the TPPs were: 1) "[i]mpact of fee changes on claim costs & premiums," 2)

"[i]mpact on plan's ability to maintain an adequate provider network that meets customers' access requirements," and 3) "[p]arity/consistency with competitor fee levels."[103]

113. It is not surprising that payors focus on prices to their customers, prices of competitors, and on whether their reimbursement rates are sufficient to attract the network and membership they seek. What this highlights is that knowledge of spreads is not necessary for competition to lead TPPs to adjust reimbursement rates to reflect the effect of spreads. Mike Beaderstadt, Director of Provider Relations for John Deere Health ("John Deere") explained this competitive process clearly when he testified that:

> [W]e'd go to minus 25 percent and nobody would sign it and we'd try minus 13 percent and everybody signed up, so we knew we had to have it somewhere in between there. And minus 20 is our latest venture there, and that has produced some headaches for us, but we have been able to put together a reasonable network based on that.[104]

114. Thus, TPPs acting in an economically rational manner will always seeks out the lowest reimbursement rate that permits them to assemble the network of physicians they seek.[105] That is, TPPs have the incentive to lower reimbursement rates until the economic incentives of the physician cause the physician to leave the network independent of payors' expectations about spreads.[106] For example, Dr. Berndt stated that:

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[103] MedPAC Study, p. 18.

[104] Deposition of Mike Beaderstadt, September 17, 2004 p. 76.

[105] Moreover, note that where TPPs offer only a single reimbursement rate to all physicians, then the rate offered must set high enough to attract the least profitable practice that the network needs. For example, BCBSMA's Mr. Mulrey, for example, noted that Massachusetts's largest payor offers all physicians the same take-it-or-leave-it fee schedule. (Deposition of Michael Mulrey, January 6, 2006 at 55:3-14.).

[106] Contracts with the TPPs are renegotiated frequently so that this price discovery process can occur regularly. For example, the study by Dyckman & Associates also showed that more than 60% of the TPPs renegotiated their contract with providers on an annual basis. (Health Plan for Physician-Administered Drugs, Dyckman Associates, August 2003, p. 14).

> [I]f health plans shift to a third party supplier of the physician-administered drugs [to reduce costs by capturing the spread], they thereby might risk losing scarce speciality physicians from their physician network who have profited from the 'spread.'[107]

115. The same mechanism suggests that even if we assume for purposes of argument that payor expectations were the critical input to the reimbursement rate, it is not necessary for all payors to be informed. Uninformed payors would observe reimbursement rates declining for informed competitors (perhaps through the kinds of public surveys used by Dr. Hartman) and less-informed competitors could respond to that information. Dr. Hartman does not account for this mechanism of competition.[108]

116. But even if Dr. Hartman's unsupported assumption that payors' expectations were the critical input to the reimbursement rate and that no payor had accurate expectations is assumed for purposes of argument, the damages estimated by Dr. Hartman would be overstated. The reason is that different payors will have different interest and ability to respond to this information. For example, Dr. Hartman has argued that some TPPs did not respond at all to information about spreads:

> Dr. Hartman:
>
> Despite the fact that publicly-available information suggesting increasing spreads became more prevalent in the latter years of the

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[107] Berndt Report at p. 42.

[108] See Hartman Deposition at 1029:16-21:

> Q. Have you attempted to analyze the extent to which competition has dissipated any of the effects of the alleged deception that you say exists within respect to physician-administered drugs?
> A. I haven't had the – the data nor I – I haven't been asked to do that, no.

See also Hartman Deposition at 855:1-12, 859:2-5, 860:4-10. Notably, if competition has already flowed through the benefits of price cutting by drug manufacturers to payors, they would benefit twice from defendants' price competition, once in the form of lower reimbursement rates and a second time in the form of damages.

> Damage Period, TPPs were not able to act on such information for the reasons cited above.[109]

The "reasons cited above" appear to be that plaintiffs would have acted no differently even if they had been aware of a difference between the actual spreads and the expected spreads:

> Dr. Hartman:
>
> payor's [sic] are not leveraged to know the extent of the AWP scheme or to act upon such knowledge, if they possessed it. Furthermore, given Dr. Berndt's research supporting the "importance of [all drug costs] being unimportant" ("The U.S. Pharmaceutical Industry: Why Major Growth in Times of Cost Containment?" Health Affairs, 20(2), 2001) relative to containment of increases in all managed health care costs, it is not surprising that the small component of all TPP reimbursements reflected by physician-administered drug costs alone, a component that is very expensive to monitor, is not subjected to scrutiny sufficient enough to adjust x% with variation in the AWP used for calculating allowed amounts.[110]

117. For such payors, elimination of the fraud by publishing spreads might not change reimbursement rates, and if so, their damages would be zero.

118. More generally, Dr. Hartman and the Court have acknowledged that differences in certain characteristics mean that changing expectations about spreads would affect TPP reimbursement rates differently.[111] For example, some physician groups may have sufficient bargaining power to keep incomes unaffected by changes in expectations about spreads. Dr. Hartman himself appears to acknowledge this when he states that to recover the full effect of the spreads above his yardstick, a payor would need not only information about the

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[109] Hartman Declaration, December 15, 2005, p. 42.

[110] Hartman Declaration, December 15, 2005, p. 20.

[111] I have discussed above why Dr. Hartman's use of a 30% discount based on a theory of revealed preferences fails to capture the range of sensitivity to spreads among payors.

spread, but market power over the physician as well. As noted previously, Dr. Hartman states that:

> Dr. Hartman:
>
> In order to avoid injury, a payor would need full information *and the market power* to force all distributors to disgorge the overcharges paid as a result of the AWP scheme. *No single payer existed* with that degree of knowledge *and that degree of market power*.[112]

119. Dr. Hartman explains that there is variance in reimbursement rates, because TPPs vary in their knowledge, negotiating skills, market power, and expectations. If so, one would not expect as Dr. Hartman's damage model assumes, that health care providers could invariably be forced to pass on 100% of their allegedly "secret discounts" in the form of renegotiated reimbursement rates. Thus, the damage estimate presented by Dr. Hartman overstates damages even if one assumes that the yardstick correctly measures expectations in the but-for world.

120. I note also that if changed payors' expectations do affect reimbursement rates, estimating damages correctly requires a case-by-case determination of what expectations were during the class period, how they would differ absent the alleged fraud, and how those differences would be reflected in reimbursement rates.

121. Figure 1 summarizes the alternative liability theories presented by Dr. Hartman and the outcomes that would result for each, none of which is consistent with his measure of damage.

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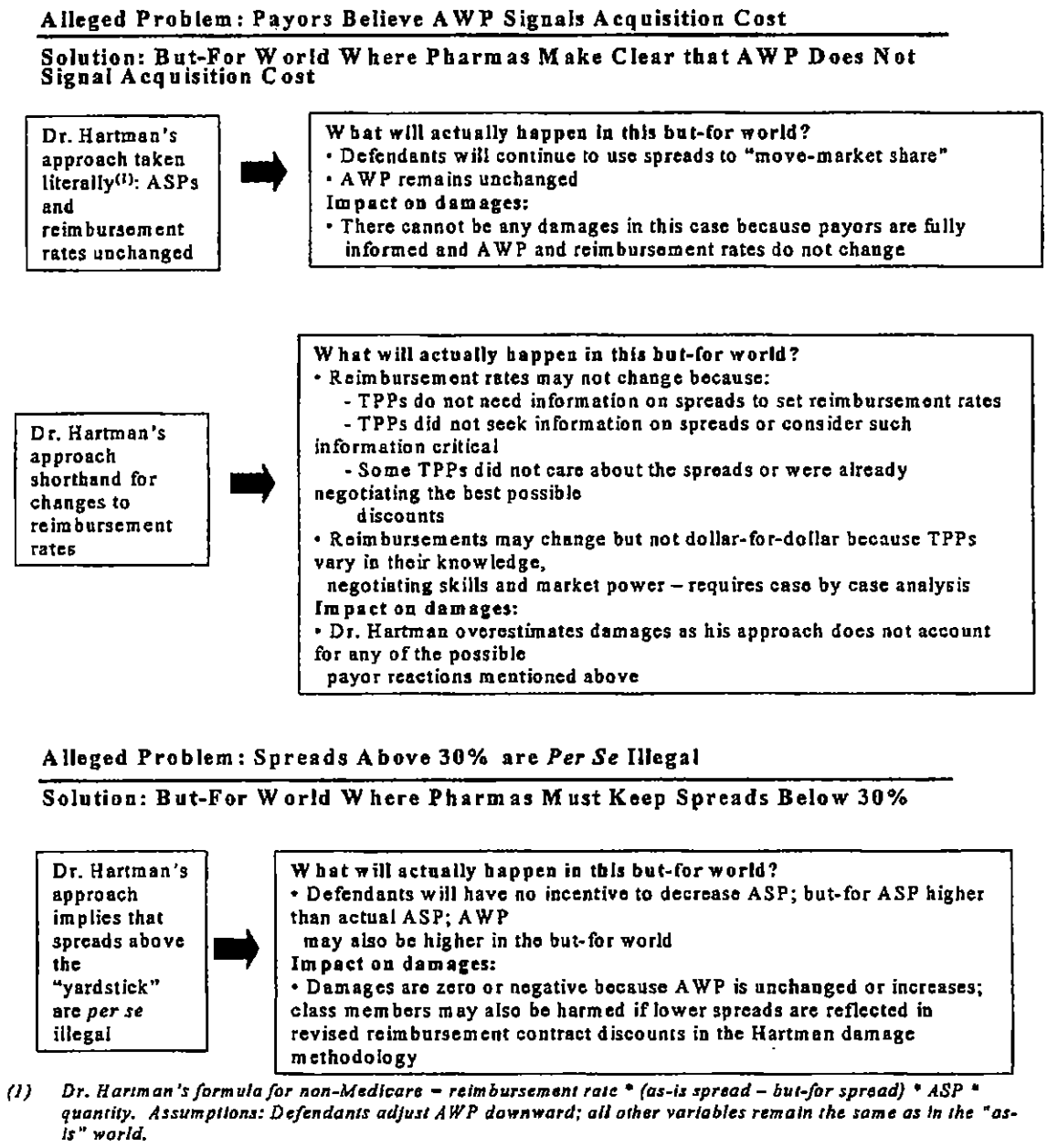
[112] Hartman Rebuttal Declaration, December 16, 2004 at FN97, p. 62.

Figure 1



*(1) Dr. Hartman's formula for non-Medicare = reimbursement rate * (as-is spread – but-for spread) * ASP * quantity. Assumptions: Defendants adjust AWP downward; all other variables remain the same as in the "as-is" world.*

B. Medicare

122. There is no relationship between a liability claim arising from plaintiffs' expectations of spreads and Dr. Hartman's Medicare damages.[113] Instead, Dr. Hartman relies on a legal interpretation of various statutes even though Dr. Hartman previously claimed no expertise in Medicare reimbursement.[114, 115]

123. Dr. Hartman changed his theory of liability for Medicare between the filing of his initial report on liability and damages and the filing of his supplement to that report. In his initial report, Dr. Hartman applied the same 30% expectations yardstick to determine liability that was applied to other payors. Dr. Hartman testified that he believed the expectations for Medicare would be the same as for other payors or that Medicare may have been more informed that private payors.[116] Despite that belief, which he applied for purposes of liability, his damages analysis for Medicare was based on a but-for spread of zero. Thus, for

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[113] Q: Doesn't the fact that the regulation distinguishes between AWP and EAC suggest that HCFA knew there was a difference between the two?
A: I *don't know what HCFA knew* So I think - I think people understood that the ASP and WAC were less than AWP, and why they wrote the regulations as they did I don't know, but I read the regulations, and if it is the estimated acquisition cost as what it is sold as, it is not sold - they don't acquire it - the physicians don't acquire it at AWP. They acquire it at an estimated acquisition cost." (Hartman Deposition, October 8, 2004, pp. 563-564, Emphasis added)

However Dr. Harman also testified that "[t]he government has set reimbursement rates that reflect an understanding that is comparable to what I would say is the -- in my yardsticks." Hartman Deposition at 672:13-16; and regarding his 30% yardstick: "So, that's for government and for non-government. That's the understanding that was in the market." (Hartman Deposition at 1235:11-14).

[114] Q: You are not an expert on Medicare regulations? Correct?
A: I am not an expert on statutory complexities of Medicare regulations."
(Hartman Deposition, October 8, 2004, p. 559)

[115] Regarding his interpretation of the Medicare statutes, Dr. Hartman testified "Q: What is it that qualifies you to offer that opinion? A: My ability to read. Q: Nothing more? A: That's right." (Hartman Deposition at 881:10-14).

[116] See Hartman Deposition at 672:7-674:19.

Medicare single-source Part B drugs until 2004, if a drug had an spread of less than 30%, Dr. Hartman argued it should have been reimbursed on the basis of AWP, as it was. If a drug had a spread of more than 30%, Dr. Hartman assumed that the drug should have been billed to Medicare and/or reimbursed at the physician acquisition cost:

> Dr. Hartman:
>
> For Medicare Part B physician administered drugs, $AWP_{but\text{-}for} = AAC = ASP$ by regulation.[48]
>
> [48] During the period 1992 through 1997, Medicare reimbursement for all Part B covered drugs was set at the lesser of the estimated acquisition cost (EAC = AAC) or national average wholesale price (AWP), as set forth in 42 C.F.R. § 405.517, which became effective on or about January 1, 1992. On January 1, 1998, 42 C.F.R. § 405.517 was amended to provide that the allowed amount would be based upon the lower of the actual charge on the Medicare claim form (interpreted to be the AAC) or 95 percent of AWP. The equality of AAC and ASP assumes that no rebates are paid.[117]

124. In the supplement to his report on liability and damages, Dr. Hartman no longer references the expectations of Medicare but assumes that liability exists for all drugs at issue in this case, *regardless* of the expected spread between AWP and ASP.[118] He offers no economic justification for this switch.

> Dr. Hartman:
>
> There are damages assessed, even though that threshold is not exceeded, which means that the relationship – there are damages assessed even when that – the spread is – does not exceed what people expected it to be.[119]

125. Mechanically, Dr. Hartman achieves this result by leaving all parameters unchanged from the as-is world and altering the but-for AWP. Of course, it is mathematically impossible to establish the but-for AWP equal to ASP (zero spread) to satisfy Dr. Hartman's claimed legal

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[117] Hartman Declaration, September 4, 2004, p. 22.

[118] Hartman Addendum to Liability and Calculation of Damages, February 3, 2006.

[119] Hartman Deposition at 1265:5-9.

requirement for Medicare, while setting the but-for AWP at a 30% spread over ASP to satisfy the alleged "market expectation" of the private sector.[120,121] Thus, there does not exist any AWP that would be consistent with both Dr. Hartman's Medicare and non-Medicare measures of liability.

126. Because it is based on a legal analysis rather than economics, I make only some limited observations about Dr. Hartman's Medicare damages theory, focusing for simplicity on his analysis of single-source drugs. First, Dr. Hartman disavows the notion that he is calculating a fraud-free AWP in his Medicare damage claims.[122] Second, Dr. Hartman's damages model assumes that PADs would be reimbursed at ASP. If this means that all payors would be reimbursed at the average price (as opposed to each physician being reimbursed based on her individual acquisition cost), the implication is that half of the PADs are administered at a loss. This would create adverse effects on incentives to provide services to Medicare patients. For example, the ASCO study which Dr. Hartman relies upon, states that for Medicare: "The payment method should be designed to fully cover the cost of drugs and not be limited to average or median surveyed costs ." (p. 32) If the payments are based on average costs, the study says that "some physicians may be systematically disadvantaged and not be able to purchase at average price ... any failure to cover an oncologist's out-of-pocket

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[120] Dr. Hartman acknowledges this point: "For this reason, I distinguish a yardstick for Medicare Part B drugs as 0.00%, merely making the point that the reimbursement rate has been set by regulation below the but-for AWP and at ASP." Hartman Declaration September 4, 2004, FN52, p. 24.

[121] Further, analogous to the quantum property of sub-atomic particles, the damage model has the property that the spread must go from 31% to 0% without ever passing through the 30% necessary to find no liability.

[122] In his deposition Dr. Hartman was unable to offer any economic explanation behind the Medicare damage claims in his supplemental damage study. At 1237:18-1238:8, he likened it to a situation where the "speed limit" is 30, but "policemen" are enforcing a requirement for Medicare payors that "they are going zero miles an hour ... they're standing still on the highway." See also Hartman Deposition at 1245:9-15, 1265:5-9. When asked at 1278:4-5, what AWP a defendant would have to publish to avoid liability under his Medicare theories, he responded, "you know, I haven't been asked to do that kind of analysis." The problem as recognized at 1279:18-21, is that "... in order to avoid that particular calculation of damages, the whole notion of industry and reporting should change ...." At 1282:2-4 Dr. Hartman states that "... it's certainly not my testimony or my opinion that the manufacturers should or did post different AWPs [for Medicare and non-Medicare]." See also Hartman Deposition at 662:3-7, 670:18-20.

expenses for drugs could easily force the physician to discontinue chemotherapy treatments."[123]

127. Finally, I note that in all cases, Dr. Hartman's damages models are incomplete. This is because Dr. Hartman ignores the impact of changes in drug reimbursement rates on related service prices.[124] To the extent that payors or physicians are concerned about the total payments to a physician for the combined drug and the care associated with administering that drug, changes in the reimbursement rate on drugs may be offset by changes in fees demanded for the related service. For example, I understand that the recent changes to Medicare Part B reimbursement to reflect ASP-based pricing for drugs in the Medicare Modernization Act have been accompanied by substantial increases in payments for drug administration.[125,126] Similarly, Mr. Mulrey of BCBSMA testified that when he analyzed a switch to ASP-based pricing for PADs, which was not implemented, he incorporated in that analysis an increase on administration fees to physicians.[127] Dr. Hartman testified that he

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[123] ASCO Study, p. 32.

[124] See Hartman Deposition at 1063:16-19, "I have focused entirely on the overcharges induced by the alleged AWP inflation and have not been asked to attempt to do any netting out against that about how other things might change."

[125] In a press release announcing the proposals that led ultimately to the changes in the Medicare Modernization Act, CMS Administrator Tom Scully explained that: "We want to make certain that Medicare pays appropriately for the drugs it covers and the costs that doctors incur when administering those drugs...Many doctors tell us they use these overpayments to supplement their office expenses. We want to make sure that we pay them higher rates for treating their patients rather than allow this unbalanced payment system to continue. We ought to pay them the right amount for drugs and services, and this proposed rule will start the process to get us there." The press release stated that "CMS is also proposing to significantly increase payments under the Medicare physician fee schedule for administering cancer drugs." See, http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=828.

[126] Dr. Hartman testified that: "[t]he industry as a whole had understandings that were reflected ultimately in the revealed rates that were negotiated - - *the revealed approaches that were discussed in Congress...*" (Hartman Deposition at 674:10-14).

[127] Deposition of Michael Mulrey, January 6, 2006 at 67:6-68:4.

does not know whether such cross-subsidization was necessary but takes his position based on a legal instruction.[128]

VII. COMMENTS ON DR. HARTMAN'S CALCULATIONS TO APPLY HIS THEORY

A. Aggregation Issues

128. In his initial declaration on class certification, Dr. Hartman stated that the calculation of spreads and relevant yardsticks can be performed by time period, by drug and/or by NDC and that he would make a final determination about these issues once the final data are produced.[129] In his report on liability and damages, Dr. Hartman performed the damage calculations at the NDC-year level but did not provide any justification for why an analysis at this level was an appropriate measure of expectations. In particular, Dr. Hartman did not conduct any tests to validate the view that payors formed expectations at the NDC level and that these expectations were updated each calendar year. As shown below, Dr. Hartman's method of aggregation is arbitrary and likely overstates non-Medicare damages by excluding data points that show spreads below his yardstick level of 30%.

129. The problem with Dr. Hartman's approach is apparent when one examines his pattern of spreads and damages across the time period considered. In several cases, an NDC of a drug goes in and out of liability and damages over time due to the spreads fluctuating above and below the 30% threshold.[130] Dr. Hartman has not offered any explanation for these patterns. At least in part, these patterns are evidence of volatility in the underlying data on ASPs which can be addressed by aggregating data over longer horizons and/or across NDCs.

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[128] Hartman Deposition at 1055:12-17.

[129] Hartman Declaration, September 04, 2004, p. 20.

[130] For example, Procrit 10,000 U/ML, Multidos shows spreads of 27.0%, 45.2%, 34.9%, 29.9% from 1995 to 1998; Intron A INJ 25MIU HSA FREE shows spreads of 23.9%, 30.5%, 35.9%, 28.6% from 1999 to 2002.

130. Given the patterns in the data, Dr. Hartman should have considered alternate methods of aggregating data. For example, he could have computed damages by aggregating across all time periods for a particular NDC or aggregating across all NDCs and period for a particular drug. In fact, such aggregations would be more consistent with Dr. Hartman's assumption that the payors' expectations did not change during the class period and that response to new information was characterized by extremely long lags.

131. Table 1 illustrates that Dr. Hartman's damages are sensitive to the way the data is aggregated. Aggregating across time periods for an NDC or across NDCs and periods for a drug, for example, lowers the calculated damages. Column 1 of Panel A shows the Sub-Class 3 aggregate damages as computed by Dr. Hartman for NDCs for which he finds liability but that had spreads less than 30% in some years.[131] Column 2 shows the results if damages are computed by aggregating across all time periods for each NDC. These damages are computed by summing Dr. Hartman's damages across time for each NDC and subtracting "negative" damages from the total. The resulting estimates are significantly lower for certain NDCs. For example, the damages go down from $0.44 million to $0.20 million for an NDC of Taxol. Panel B shows the results if damages are computed by aggregating across time periods and NDCs for certain drugs.[132] This approach yields even lower figures with Procrit and Introl showing zero damages against a 30% yardstick.

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[131] Note that the table does not include damages for years in which Hartman extrapolated data to fill in the figures for years in which he had missing data; thus, the damages attributed to Dr. Hartman's methodology (in column 1) are different from the totals listed in his report.

[132] These damages are computed by summing Dr. Hartman's damages across time and NDCs for each drug and subtracting "negative" damages from the total. The negative damages are obtained for those years and NDCs in which the spread for is less than 30%. This approach is equivalent to estimating a revenue weighted-average spread for each drug and then applying the weighted-spread to all years and NDCs of that drug. If the weighted-spread is less than 30% for any drug, damages are set to zero for that drug.

Table 1: Summary of Damages Using Alternate Methods of Aggregation

			Non-Medicare, TPPs and Consumers (Massachusetts– Sub-Class 3)	
Company	Drug	NDC	Dr. Hartman's Estimates (1)	Aggregation Across Years/Across NDCs and Years (2)
Panel A				
Bristol Myers-Squibb	Taxol	00015347911	$436,107	$199,831
Johnson & Johnson	Procrit	59676032001	$264,112	$163,413
Schering-Plough	Intron	00085053901	$176,536	$123,489
Panel B				
Bristol Myers-Squibb	Taxol	All	$725,791	$257,524
Johnson & Johnson	Procrit	All	$857,924	$0
Schering-Plough	Intron	All	$998,399	$0

Notes and Sources:

(1) Dr. Hartman's estimates are the damages he calculated in his December 15, 2005 Declaration. The damages will not match those listed in the report because the table does not include Dr. Hartman's extrapolation to years not covered in the data.

(2) These damages are computed by summing Dr. Hartman's damages across time and NDCs for each drug and subtracting "negative" damages from the total. The negative damages are obtained for those years and NDCs in which the spread for is less than 30%.

B. Computation of ASP

132. In his supplemental declaration of February 2006, Dr. Hartman revises his computation of ASP by including data on certain hospitals and HMOs.[133] The result of this revision is that for many drugs the ASP (spread) is significantly lower (higher) than what was computed in his December 15, 2005 declaration. Consequently, many NDCs that were below the 30% liability threshold in the earlier Declaration crossed the threshold in the supplemental Declaration. Table 2 shows examples of such NDCs.

133. The substantial change in the ASPs and spreads cast doubt on Dr. Hartman's liability theory and damage methodology. In particular, the results in Table 2 undermine Dr. Hartman's key liability assumption that the AWP is a signal for ASP calculated for PADs in this proceeding. It is evident that the same AWP is associated with several different ASPs; the ASPs for hospitals and HMOs are lower than those for physicians in many cases. Moreover, calculating a single ASP over all classes of trade solves the multiple-ASP problem, but only by creating another problem for the damage calculation. If there is a significant difference in ASPs by class of trade as the patterns in Table 3 suggest, it is not justifiable for Dr. Hartman to include hospitals and HMOs in the calculations for ASP in his damage calculation. The mixing of the classes of trades leads to an overestimation of damages at the aggregate level for physician-administered drugs, because class members are being awarded damages due to larger spreads to non-class members (hospitals and HMOs). Table 2, in fact, shows that calculating damages based on the revised ASPs will award damages to class members for certain drugs even though prices to their providers do not create spreads that exceed their expectations as measured by the Hartman "yardstick."

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[133] For example, for BMS Dr. Hartman includes data on civilian hospitals, community health care clinics, and various types of HMOs. These data were not included in the calculation of ASP in the December 15, 2005 Declaration.

Table 2: ASPs and Spread in Supplemental vs. Original Declarations

Drug	NDC	Year	Original ASP ($)	Original Spread (%)	New ASP ($)	New Spread (%)
Cytoxan	00015054812	1998	41.14	25.01	19.40	165.08
Taxol	00015347520	2000	146.10	25.00	135.11	35.17
Vepesid	00015309530	1996	108.00	26.38	66.82	104.26
Kytril	00029415105	1999	694.43	29.16	634.87	41.27
Lanoxin	00173026035	1997	79.79	20.69	55.88	72.34
Ventolin	00173038558	1992	12.23	21.52	9.88	50.42
Zofran	00173044702	1999	2,025.16	25.34	1,799.71	41.04
Intron	00085057106	1997	496.90	26.82	394.69	59.66
Proventil	00085020901	1991	26.39	18.00	21.70	43.52

Notes and Sources:

(1) Original ASP and Spreads source: Hartman workbooks "X Liability Damages.xls", where X is the respective defendant.

(2) New ASP and Spreads source: Hartman workbooks "X Liability Damages - Revised ASP.xls", where X is the respective defendant.

C. Assumption of 97.5% Reimbursement Rate

134. In computing damages for drugs in Sub-Class 3, Dr. Hartman applies a reimbursement rate of 97.5% to all NDCs and all time periods. He justifies this assumption by referencing the survey conducted by Dyckman & Associates on behalf of MedPAC in 2002. That survey provided information on average reimbursement rates for AWP for 32 Health Plans and showed that the average (of the average reimbursement rate) across all plans was 97.5%.[134]

135. Notwithstanding the sample selection, geographic scope, and temporal issues of the survey, the reimbursement rates cited by the survey for each TPP was the *average* for that payor. An average does not reveal information on the degree of variation in the data points that are averaged. As a result, a payor might reimburse physician groups at different rates and the different reimbursement rates may be associated with different drug usage patterns. For example, a TPP with an average reimbursement rate of 97.5% of AWP might be reimbursing two different drugs at 88% and 108% of AWP, respectively. In such a case, applying a 97.5% average to each drug will generate unreliable estimates of damages.

136. This problem is illustrated in Table 3, which presents the J-code level distribution of reimbursement rates for five drugs for Blue Cross and Blue Shield of Kansas City (BCBS KC).[135] The distribution for each J-code is generated using transaction-level data on reimbursements by BCBS KC to various providers. As shown in the table, there is a wide variation in reimbursement rates across these drugs.[136] For example, for Taxol, less than 1%

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[134] MedPAC Study, p. 17.

[135] A "J-code" is a code established by the Centers for Medicare and Medicaid Services (CMS) to enable the providers/physicians to bill for the drugs administered in their offices.

[136] The reimbursement rates are computed by taking the ratio of the "allowed amount" in the BCBS KC data to the AWP data provided by Dr. Hartman. The AWP is adjusted to a per unit value by using the units listed in the crosswalk "January 2006 ASP NDC-HCPS Crosswalk" taken from www.cms.hhs.gov. The transactions that were plausibly not based on AWP are omitted. These include reimbursements to "outside the network" providers, reimbursements to hospitals, and reimbursements for drugs facing generic competition. The transactions referencing Medicare-related reimbursements were also dropped as they do not apply to Sub-
(continued...)

of transactions showed a reimbursement rate less than 85% of AWP, while more than 75% of the transactions showed a reimbursement rate of more than 85% of AWP. On the other hand, for Navelbine, the corresponding figures were 30% and 43% of transactions. The weighted-average reimbursement rate for Taxol is 96.4% while it is 87.6% for Navelbine. This variation demonstrates that Dr. Hartman's methodology of using a TPP level average reimbursement rate and then averaging the reimbursement rates across all plans (to arrive at an overall number of 97.5% to be applied to each NDC) is unreliable. It will lead to incorrect estimates of damages for individual defendants whenever the drugs that are the subject of the litigation have reimbursement rates that differ from the average.

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[136] (...continued)
Class 3. The "Unclear" category includes transactions that were odd multiples of AWP (*e.g.* 200% of AWP) and thus reflect errors in units, as well as other reimbursement rates that did not have a clear relationship to AWP. It is assumed that all remaining transactions were based on AWP, although it should be noted that for a sizeable portion of these transactions the reimbursed amount equaled the "billed charge". To the extent that the billed charge is not based on AWP, these transaction were also not linked to AWP. This problem can only be resolved through case-by-case inquiry.

Table 3: Reimbursement Rates by BCBS Kansas City

	Distribution of Reimbursement Rates (%) by Drug / J-Code				
Reimbursement Rate as % of AWP	**Zoladex J9202**	**Taxol J9265**	**Imitrex J3030**	**Navelbine J9390**	**Remicade J1745**
71-75	0.15	0.04	1.66	18.44	0.7
76-80	0.23	0.17	7.46	2.46	3.07
81-85	5.56	0.46	10.5	9.67	5.87
86-90	13.39	8.09	5.52	7.09	1.35
91-95	39.88	8.21	20.72	15.44	72.68
96-100	24.43	59.98	10.77	18.98	3.45
101-105	2.44	1.63	12.98	3.24	0.59
Unclear	13.93	21.43	30.39	24.68	12.28
Total	*100.00*	*100.00*	*100.00*	*100.00*	*100.00*
Weighted Average Reimbursement Rate	93.20%	96.41%	91.65%	87.55%	91.83%
Number of Transactions	1,314	2,399	362	1,665	1,856

Notes and Sources:

(1) Payor data provided by BCBS Kansas City.
(2) AWP data provided by Dr. Hartman.
(3) Payor data is modified to exclude: adjustments, zero reimbursements, Medicare transactions, "Outside" network providers, and reimbursements to hospitals.
(4) Analysis is restricted to time period before drug became generic, if applicable. The time periods for each drug are: Zoladex (1995-2004); Taxol (1998-2001); Imitrex (1995-2003); Navelbine (1995-2003); Remicade (2000-2003).
(5) "Unclear" refers to transactions with reimbursement rates that fall outside 71% - 105% of AWP. These include transaction that are odd multiples of AWP (*e.g.* 200% of AWP) and thus reflect errors in units.
(6) Weighted Average Reimbursement Rate calculation excludes transactions considered "Unclear"

D. Use of NAMCS Data

137. Finally, Dr. Hartman uses data from the National Ambulatory Medical Care Survey (NAMCS) to allocate total sales of physician administered drugs between Medicare Part B and non-Medicare payors. It appears that for some drugs, Dr. Hartman has relied on very few observations to estimate the allocations. The National Care for Health Statistics (NCSH) which conducts the NAMCS survey warns that estimates based on fewer than 30 records are unreliable.[137] In particular, reliance on very few observations implies that there is imprecision in the estimation of Medicare/non-Medicare proportions which could have a significant impact on the damages estimates. The NAMCS data has 8 observations for Alkeran, 9 for Navelbine, 7 for Retrovir, and 9 for Intron.

[137] 2003 NAMCS Micro-Data File Documentation, p. 7.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on: March 21, 2006

By: Daniel L McFadden
Daniel L. McFadden

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO 01-CV-12257-PBS AND 01-CV-339	Judge Patti B. Saris

MERITS REPORT AND DECLARATION OF FIONA SCOTT MORTON, PH.D.

March 22, 2006

54. Plaintiffs endow every payor with remarkably simplistic expectations: its expectation of the spread does not vary with the drug, therapeutic class, buyer characteristics, or the market. In particular, Plaintiffs' theory is that payors form expectations based on a brand name drug's "spread" while it is a single-source drug, and continue to expect exactly the same "spread" once the drug encounters therapeutic or generic competition (without ever learning that the "spread" may differ over the product lifecycle).[79] Plaintiffs' theory does not incorporate even the most rudimentary characteristics of economic markets or the pharmaceutical industry, not even those characteristics acknowledged by third-party payor deponents in this matter.[80]

5. Plaintiffs' theory would require manufacturers to know payors' expectations

55. According to Plaintiffs, manufacturers also have to establish prices that fall within an acceptable range of payors' expectations of "spreads" to avoid fraud. However, payors' expectations are not published or communicated to manufacturers in any formal manner; nor are manufacturers privy to negotiations and other communications between payors and providers. Given the lack of reliable information on payors' expectations, Plaintiffs do not explain how manufacturers could avoid the alleged fraud.

56. More specifically, Plaintiffs' theory would require generic manufacturers to be aware of payors' expectations to avoid fraud. This would be a remarkably difficult feat because, while parties knowledgeable about the industry know there would be significant discounting upon generic entry, no one can accurately predict the intensity of price competition and thus expectations would be expected to vary a great deal. Price competition would depend on many factors, including how many

[79] Hartman Liability Report, ¶ 22.

[80] For example, Harvard Pilgrim Health Care purchased drugs directly from manufacturers for its staff model HMOs in Massachusetts, thereby learning that single-source spreads and multi-source drug discounts were substantial and differed. See Kenney Deposition (Harvard Pilgrim Health Care), pp. 11–15. I discuss other characteristics of pharmaceutical markets in section III.C.–III.E.

generic firms entered, on what dates, and with what capacities. Again, Plaintiffs' theory does not incorporate well-known aspects of competition in the pharmaceutical industry.

6. Plaintiffs' theory of slow formal institutionalization of new information is arbitrary and self-serving

57. When asked how payors could not have been aware of the existence of so-called "mega-spreads" from the very same government reports that he cites, Dr. Hartman suggests that payors were slow to formally institutionalize such new information, although he provides no economic analysis to support any theory of learning. Dr. Hartman suggests that payors did not "institutionally understand" such information on multi-source "spreads" in the 1992 OIG report until around 2004 to 2006.[81] However, apparently Dr. Hartman believes that payors understood the information on smaller *single-source* drug "spreads" immediately, for he contends that this 1992 report informed payors' expectations throughout the class period,[82] which begins in 1991. These positions are clearly arbitrary and self-serving. Drs. Hartman and Rosenthal do not offer any support in the economic literature for such a paradoxical pattern of institutional learning, and if payors truly thought providers' acquisition costs were important for setting reimbursement rates, they would not disregard large "spreads" that in later periods Dr. Hartman describes as flabbergasting them.[83]

7. Dr. Hartman applies a fixed "liability threshold" to changing expectations

58. In deposition testimony, Dr. Hartman acknowledged that payors' expectations of "spreads" have changed over the past 15 years.[84] However, he applies an unchanging "liability threshold" throughout his liability analysis. Similarly, Dr.

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[81] Hartman Deposition, pp. 764–768, 840–841. Dr. Hartman refers to the 1992 OIG Report.

[82] Hartman Deposition, pp. 726–727, 764–766.

[83] Hartman Deposition, p. 770. Dr. Hartman adopts this term from a comment made by an AdvancePCS executive in a telephone interview, excerpts of which are reported in "AdvancePCS Views its Specialty Rx as Complementary to Caremark's Approach," *Specialty Pharmacy News*, Vol. 1, No. 2, March 2004, pp. 1–3.

[84] Hartman Deposition, pp. 784–785.

Hartman applies an unchanging but-for "spread" in his damages analysis. These flaws are symptomatic of the inability of Dr. Hartman's methodology to incorporate any increased knowledge or meaningful variation in the economic factors that may influence pricing or expectations in the pharmaceutical industry.

B. Dr. Hartman's "revealed preferences" theory is biased and unreliable

59. Notwithstanding payors' statements to the contrary,[85] Dr. Hartman contends that Medicare statutes and private payors' negotiations reveal that payors expected there to be a predictable relationship between AWP and acquisition costs for reimbursement purposes. However, from the standpoint of economic theory, the only fact revealed by a reimbursement rate (in a statute or private contract) is the *price* both parties have agreed to use for reimbursement purposes; a reimbursement rate says nothing about payors' *preferences*, nor their expectations about providers' acquisition costs. This transaction price is the outcome of a negotiation between payors and providers in which payors try to bargain down providers to the lowest rate the providers are willing to accept, while providers try to extract the highest rate they can from payors. The expectation each party regarding operating costs of the other party—if any—is an entirely different topic. It is conceivable that the negotiated result would not meet the expectations of one or both of the parties. Dr. Hartman does not provide a testable hypothesis as to how reimbursement rates could reveal any preferences of providers.

60. The reimbursement rates that physicians seek are driven by their practice expenses, which, by and large, do not depend on AWP—insurance, rent, nursing staff salaries, supplies, etc. Regardless of the reimbursement benchmark used by payors, physicians would seek to cover practice expenses and maintain an acceptable profit margin. Medicare Part B policymakers publicly acknowledged the importance of paying providers enough in total to assure their participation in the program. In several cases where Medicare reduced overall drug reimbursement without increasing reimbursements for drug administration, they observed that many

[85] See section III.C.1.

providers found it financially unviable to continue participating in the Part B program.[86] Similarly, private payors testified in this matter that they negotiated on the overall bundle of drugs and services in the fee schedule, and when providers objected to the fee schedule payors increased it across the board by a mutually agreeable percentage (rather than renegotiating the reimbursement for each item individually).[87] Payors' focus on overall payments to providers allowed there to be substantial variation in "spreads" across individual drugs.

61. Dr. Hartman contends that when payors have sufficient information, their preferences are revealed in actions, such as setting the terms and rates of reimbursement.[88] However, his "revealed preferences" approach is unable to detect most types of reimbursement policy change except complete abandonment of AWP. In fact, Dr. Hartman's approach is biased and unreliable for several reasons.

62. First, Dr. Hartman's approach ignores numerous actions by payors that were clearly motivated by institutional knowledge, including implementation of Least Cost Alternative programs, implementation of Maximum Allowable Cost ("MAC") programs, Medicare policy changes in the wake of the *Barron's* "Hooked on Drugs" article, constant efforts to reform reimbursement by the Department of Health and Human Services ("HHS") throughout the 1990s, and various changes in Medicare Part B statutory reimbursement rates to reduce program expenditures. These numerous reforms also demonstrate that PAD reimbursement was not "unimportant" to payors.[89]

63. Second, Dr. Hartman's approach ignores payors' conscious decisions not to change reimbursement methods despite awareness of so-called "mega-spreads." For example, Blue Cross Blue Shield of Massachusetts ("BCBSMA") decided not to switch to an ASP+6 percent reimbursement regime since it might lead physicians to

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[86] See section III.C.4, which provides examples of Medicare changes to reimbursement for chemotherapy drugs and intravenous immunoglobulin.

[87] See section III.C.4.

[88] Hartman Deposition, pp. 823–824.

[89] See section IV.B.5.

withdraw from its provider network, rendering it unviable.[90] Despite testimony that BCBSMA consciously chose not to switch to an ASP-based reimbursement system for PADs, Dr. Hartman concludes that payors were stymied by "various institutional reasons and information technology reasons you are locked into a certain reimbursement system that was based on other expectations."[91]

64. Third, since Dr. Hartman's approach is only designed to detect changes, it cannot account for payors' purposeful and ongoing use of spreads to provide incentives to physicians, such as encouraging a shift in care out of hospitals and ensuring physicians' participation in provider networks.[92]

65. Fourth, Dr. Hartman admits that expectations differ "quite a bit" from contract prices.[93] Thus, it is likely that what is revealed by contract reimbursement rates—if anything—is not very precise and, in any case, not accounted for in Dr. Hartman's comparisons of his liability threshold to actual "spreads."

C. Plaintiffs' expectations theory is explicitly contradicted by payors

1. Medicare and private payors did not expect there to be a predictable relationship between AWP and providers' acquisition cost

66. Dr. Hartman relies on a 1992 OIG report that covered 13 chemotherapy drugs, but does not report the key findings of that report, which payors would have known when forming their expectations: "AWP is not a reliable indicator of the cost of a drug to physicians"[94] and "[c]onsidering that we also found that there is no single discount rate which can be applied to the AWP to provide a reasonably consistent estimate of physicians' acquisition cost, we do not feel that AWP provides a useful

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[90] Deposition of Michael T. Mulrey (Manager of provider reimbursement within the actuarial area, BCBSMA), January 5, 2006 ("Mulrey Deposition"), pp. 5, 65–73, 129–130. See, also, Hartman Deposition, pp. 828–834, and Hartman Deposition Ex. 35 ("Analysis of CMS Average Wholesale Price Reform," February 7, 2006, which is also marked as Mulrey Deposition Ex. 2): p. 12.

[91] Hartman Deposition, pp. 840–841.

[92] See section IV.D.

[93] Hartman Deposition, pp. 784–785.

[94] 1992 OIG Report, p. 2 (which includes a cover letter from William Toby, Jr., Acting Administrator, Health Care Financing Administration).

measure of the acquisition cost for a drug to physicians."[95] Dr. Hartman also ignores one of the key findings of the 1997 OIG report he references: AWPs "bear little or no resemblance to actual wholesale prices that are available to the physician and supplier communities."[96]

67. Dr. Hartman did not analyze the legislative or statutory history of Medicare Part B,[97] which would have revealed the fallacy of his expectations theory. In January 1998, the head of the HCFA wrote to Representative Stark that "while Medicare policy is to pay at the average wholesale price (AWP) for drugs, the prices reported by the commercial sources of this information do not accurately reflect the true wholesale price in the marketplace. We have been aware of this problem..."[98] In a 1999 report to Congress, the head of the Department of Health and Human Services concluded with "the OIG finding cited earlier in this report that, as an unregulated, suggested price, typically set by the manufacturer, the AWP bears no consistent or predictable relationship to the prices actually paid by physicians and suppliers to drug wholesalers in the marketplace."[99]

68. Dr. Hartman also ignores the testimony of private payors, some of whom either did not expect a predictable or consistent relationship between AWP and providers' acquisition costs[100] or had no expectations of it at all.[101]

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[95] *Ibid*, Appendix II; also, "...the Red Book does not represent its AWP as a measure of the physician's acquisition cost for drugs...".

[96] 1997 OIG Report, p. ii. See, also, Hartman Declaration of Sept. 3, 2004, Attachment D: fn. 10.

[97] Hartman Deposition, pp. 806–807, 923.

[98] Letter from Nancy-Ann Min DeParle to Representative Fortney Pete Stark, January 26, 1998, HHC001-0363–366 at HHC001-363.

[99] Shalala, Donna E., Secretary, Department of Health and Human Services, *Report to Congress: The Average Wholesale Price for Drugs Covered Under Medicare*, 1999, HHC902-0801–18 ("Shalala Report to Congress, 1999") at HHC902-0802–9.

[100] See Deposition of Joe Spahn (Senior health care consultant, Anthem BCBS), November 30, 2004 ("Spahn Deposition"), pp. 20, 97–98 (no particular expectation) and Hartman Deposition, pp. 760–769; and Deposition of Mike Beaderstadt (Director of Provider Relations, John Deere Health Plan), September 17, 2004 ("Beaderstadt Deposition"), pp. 72–73 (no "consistent" relationship).

[101] See Killion Deposition (BCBSMA), pp. 138–139; Deposition of J. Russell Hailey (Chief Pharmacy Officer and Vice President of Pharmaceutical Services, Coventry Health Care), August 4, 2004

2. Plaintiffs allege that each payor formed the same "spread" expectation for each drug, contrary to results of surveys they relied upon

69. Plaintiffs allege that each payor developed a similar range of expectations regarding the "spread" (Dr. Hartman's so-called "market expectations"), and that payors did so in part by relying upon overall averages from particular government surveys and reports.[102] One of the sources cited by Dr. Hartman as corroborating his view—MedPAC—actually found that payors reported using different reimbursement formulae (in particular, discounts) for different categories of drugs, such as chemotherapy, immunizations, and vaccines.[103] Health plan deponents in this matter have also acknowledged that providers' margins may vary across drugs.[104]

70. Note that Dr. Hartman's contention that his sources of information regarding "spreads" corroborate one another[105] is most certainly false. If he had reported the full range of "spreads" reflected in each of these reports, the ranges would be much wider and would not be in agreement with his hand-picked figures for single-source drugs.[106]

3. Payors understood that "spreads" were larger for multi-source drugs, and thus would not expect single-source drugs to serve as "yardsticks" for "spreads"

("Hailey Deposition"), pp. 6, 151–152; and Deposition of Gary Owens (Vice President of medical management and policy at Independence Blue Cross), July 22, 2005 ("Owens Deposition"), pp. 6, 162.

[102] Hartman Declaration of Dec. 16, 2004, ¶¶ 15 (i), 51.

[103] MedPAC, *Report to Congress: Variation and Innovation in Medicare*, June 2003 ("2003 MedPAC Report"), p. 166. This report presents the findings of a survey of approximately 33 health plans performed for MedPAC; see MedPAC, *Health Plan Payment for Physician-Administered Drugs*, A study conducted by Dyckman & Associates, August 2003, No. 03-5, pp. 1 and 3.

[104] Spahn Deposition (Anthem BCBS), pp. 58–59; Deposition of Dan Dragalin (Executive Vice President in charge of the network, Multiplan), September 17, 2004, pp. 9, 99–100.

[105] Hartman Liability Report, ¶ 22.

[106] See section IV.A.

71. A cornerstone of Plaintiffs' theory is that payors formed expectations of the "spread" from available information, and single-source brand name drugs serve as a reasonable "yardstick" for this information.[107] This implies that payors did not have a different expectation of "spreads" for single-source and multi-source drugs, and did not update their expectations when a drug encountered therapeutic or generic competition.

72. Several health plan deponents in this matter have contradicted Plaintiffs' theory. Harvard Pilgrim Health Care, a large health maintenance organization in Massachusetts, purchased brand name drugs from manufacturers at a price of 2 percent to 50 percent off WAC, and generic drugs for 50 percent to 80 percent off WAC.[108] BCBSMA, CIGNA, and Independence Blue Cross, for example, understood that increased price competition causes a reduction in the prices of generic drugs.[109]

73. CMS, and other government agencies that routinely study the Medicare and Medicaid programs, have acknowledged the differences in acquisition costs between single-source and multi-source drugs. For example, a 1997 OIG report cited by Dr. Hartman clearly recognized the difference, finding "average discounts of 18.30 percent below AWP and 42.45 percent below AWP, respectively" for brand name and generic drugs.[110] In a report for CMS, Stephen Schondelmeyer explained that generic drugs generally have larger (and more variable) "spreads" than branded drugs, generally causing the difference between AWP and acquisition costs to be higher for generic than branded drugs.[111]

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[107] Hartman Liability Report, ¶ 22 (a).

[108] Kenney Deposition (Harvard Pilgrim Health Care), pp. 12–13.

[109] Killion Deposition (BCBS MA), pp. 120, 126–129; Deposition of Jill S. Herbold (Assistant Vice President Practitioner Reimbursement, CIGNA), January 14, 2005 ("Herbold Deposition"), pp. 6, 36–37, 86; Kenney Deposition (Harvard Pilgrim Health Care), pp. 12–13; Owens Deposition (Independence BC), p. 136.

[110] OIG, *Medicaid Pharmacy: Actual Acquisition Cost of Brand Name Rx Drug Products*, A-06-00-00023, August 10, 2001, p. 1. See Hartman Declaration of Sept. 3, 2004, Attachment D: ¶ 21.

[111] Schondelmeyer, Stephen W. and Marion V. Wrobel, *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices*, Abt Associates, Inc., August 30, 2004, p. 18; see, also, p. 7 ("Most experts

74. Lastly, payors clearly understood that the entry of generic competitors results in price competition that generally reduces the total cost of health care. Many payors have implemented differential dispensing fees[112] and patient co-payment provisions that encourage the use of generic prescription drugs precisely for this reason. It is simply not credible to assume that payors have forgotten the lesson that competition lowers prices when setting reimbursement rates for physician-administered drugs.

4. Payors focus on the total payments to providers, not reimbursement for each drug individually as Plaintiffs' assume, creating variation in "spreads" across drugs

75. Dr. Hartman fails to recognize that the *total* payment is of greater consequence to providers than the division between drug and service components. Medicare policymakers are aware of physicians' concern over the total reimbursement they receive, because only if the total payment is sufficient would physicians be able to cover the costs of the drug, drug administration, and other related practice expenses. For example, CMS and Congress openly discussed cross-subsidization of drug administration fees in revising chemotherapy drug reimbursement rates under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") (and earlier). Officials were concerned that if they cut reimbursement too far, physicians would cease to serve Medicare patients.[113]

76. In fact, Medicare Part B reimbursement rate reductions have in some instances made it financially impractical for physicians to provide PADs in their offices, forcing patients to seek treatment in hospitals where the costs of care are higher. Two prominent examples are chemotherapy under Medicare's Part B in the late

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agree that AWP, or even the typical discounts to AWP, exceed actual acquisition costs for both pharmacies and physicians. This is particularly true for generic drugs"). See, also, Berndt Report, ¶ 47.

[112] See section IV.D.5.

[113] Letter from members of Congress to Donna E. Shalala, Secretary of the Department of Health and Human Services, July 28, 2000, accessible at http://www.asco.org/prof/pp/html/m_0800shalaltr.htm ("Letter from members of Congress to Shalala, 2000"), p. 1.

1980s,[114] and intravenous immunoglobulin ("IVIG") under the Medicare Modernization Act's shift from AWP to ASP-based reimbursement.[115]

77. Another factor that caused "spreads" on Medicare Part B drugs to vary during the class period was inconsistency in Medicare carriers' setting of reimbursement rates for J-codes. As a result, reimbursement rates differed by 10 percent or more across Medicare carriers for the same drug for some of the most costly physician-administered drugs.[116] This variation in actual spreads is the result of Medicare policy and carriers' practices, not the behavior of drug manufacturers;[117] in any case, Dr. Hartman fails to grapple with it because he uses published AWPs instead of actual reimbursement rates.

78. Dr. Hartman completely fails to recognize that in negotiating reimbursement rates with a physician practice, insurers are ultimately concerned about the *total* costs of including the practice in its network, since that is what affects the premiums it would have to charge purchasers of its insurance plans. Health plan deponents in this matter have testified regarding their practice of negotiating with providers over the total reimbursement reflected in a fee schedule rather than negotiating each item individually.[118] Because providers' abilities to secure discounts (and thus their

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[114] Dougherty, Elizabeth and Dawn Hagin, "Market Memo: Move Quickly, but Cautiously in Outpatient Cancer Care," *Health Care Strategic Management*, Vol. 7, No. 2, February 1989 ("Dougherty and Hagin, 1989"), p. 18.

[115] "CMS Responds to IVIG Availability Concerns with Add-on Payments for Outpatient Use," *Specialty Pharmacy News*, Vol. 2, No. 12, December 2005, pp. 1–3 ("2005 CMS IVIG Article") at 1–2.

[116] OIG, *Medicare Reimbursement of Prescription Drugs*, OEI-03-00-00310, January 2001 ("2001 OIG Report"), pp. 8–9, Appendix C.

[117] The variation arose because a HCPCS code (J-code) could correspond to anywhere from one to ten NDC codes, which could represent one or more chemical compounds (or different forms, strengths, or packaging), and each carrier could choose different NDCs in developing an "AWP" (i.e., the lowest, median, etc.) to use in determining the J-code reimbursement rate. In addition, carriers updated their AWP calculations at different time intervals. To address this problem, on January 1, 2003, CMS implemented the Single Drug Pricer (SDP) program under which CMS centrally develops AWPs and then distributes them to carriers. CMS chose Palmetto GBA to determine AWPs for the program. The SDP was expected to save the Medicare program $50 million annually. See 2003 MedPAC Report, pp. 154, 160.

[118] Deposition of Susan Johnson (Manager, Medical Policy Support unit, Aetna), March 16, 2005 ("Johnson Deposition"), pp. 6, 101–102; Spahn Deposition (Anthem BCBS), pp. 57–59, 107–110;

acquisition costs) vary across drugs they purchase, it is readily apparent that providers' "spreads" can be expected to vary across drugs.

79. If physicians were to agree to lower reimbursement rates for one line item—such as drugs—they would have to seek higher reimbursement on another item—such as drug administration fees—to cover the same overall practice expenses. Because this process would be time-consuming and would not ensure sufficient total payments to providers, negotiations with private payors are not conducted in this way. A fee schedule for the bundle of all drugs and services is presented,[119] and a physician or his group negotiates for an overall increase (e.g., 2 percent, 5 percent, 10 percent) on all items in the fee schedule if they find the contract to be unacceptable.[120]

80. Contracting for a bundle of services is likely to minimize transactions costs for insurance companies. Providers are partly responsible for controlling costs such as drug acquisition costs, whereby they may select the appropriate treatments while keeping in mind the total costs of care. It may be easier for the insurer to evaluate the total cost for the bundle of services—for example, by examining the average historical cost of treating patients with a particular disease across many physicians—than to estimate precisely each element. Of course, by contracting for the bundle the insurer also avoids spending resources on micro-managing costs that may be better handled by the provider. Each provider has an incentive to control the costs of care because the insurer can stop contracting with the provider if the quality of service is poor[121] or costs too much.[122]

Owens Deposition (Independence BC), pp. 31–32 (experiences at Delaware Valley HMO), 37–40 (experiences at IBC).

[119] Payors sometimes carve out specific high-cost items to be handled separately, although these items also influence the total payments to providers.

[120] Owens Deposition (Independence BC), pp. 31–32, 37–40.

[121] "Plans have cancelled contracts with physicians who have not met preset [quality of care] standards. Additionally, when periodic reviews by state and/or federal agencies have uncovered quality deficiencies, they have withdrawn approval for physician participation in managed care contracts.".

5. Many payors have no ASP expectation, and would not change drug reimbursement if they had more precise knowledge of "spreads"

81. A cornerstone of Plaintiffs' liability theory is that payors needed to know the relationship between providers' acquisition costs and AWP in order to determine reimbursement rates, and that gaining additional information on the topic would cause them to change their reimbursement rates. Notwithstanding the plentiful information available to payors, payors generally do not use information on providers' acquisition costs in setting reimbursement rates. Therefore, Plaintiffs' assumption is invalid for two reasons.

82. First, Plaintiffs' assumption that buyers need to know sellers' costs is simply incorrect as a matter of economics. The Federal Trade Commission ("FTC") has concluded that buyers do not need information on the sellers' cost structures to make efficient purchasing decisions in the overwhelming majority of markets.[123]

83. Second, Plaintiffs' assumptions are wrong for both Medicare and private payors. The public debate surrounding various Medicare reforms confirmed that Congress did not intend to reimburse Part B providers at acquisition costs.[124] Even though Medicare adopted a regulation setting reimbursement at the lower of AWP and EAC (as established by surveys), the surveys were never conducted and the EAC

Shalowitz, Joel I., "Reimbursement Trends in Clinical Oncology: Payment and Quality Issues," *Cancer Investigation*, Vol. 7, No. 3, 1989, pp. 277–282 at 281.

[122] Short, Ashley C. et al., "Provider Network Instability: Implications for Choice, Costs and Continuity of Care," Center for Studying Health System Change, *Issue Brief No. 39*, June 2001.

[123] "In the overwhelming majority of markets, however, consumers have limited or no information about the cost structure of those with whom they do business. More importantly, in general, consumers do not need such information to make efficient purchasing decisions. Instead, consumers make purchasing decisions based on the price and value of goods and services, without regard to a vendor's costs of production." Federal Trade Commission ("FTC"), Letter from the FTC to Assembly Member Greg Aghazarian, regarding California Assembly Bill No. 1960, September 7, 2004 ("FTC Letter to California Assemblyman, 2004"), p. 8.

[124] See the introduction by Senator John Ashcroft of bill S. 3003 (Cancer Care Preservation Act) in the Congressional Record for the 106th Congress, Senate, September 5, 2000, S8019–S8023 ("2000 Ashcroft Statement to the Senate"), at S8022.

part of the regulation was never implemented.[125] The Administration determined the EAC surveys to be burdensome, unfeasible, and unlikely to be statistically valid.[126] When the Clinton Administration proposed legislation in 1997 to change the reimbursement rate to actual acquisition cost, Congress rejected that proposal.[127] Congress, CMS, and other government agencies understood that Part B drug reimbursement cross-subsidized other inadequately reimbursed (or unreimbursed) services and practice expenses.[128] Due to the implementation of ASP + 6 percent pricing under the MMA, Medicare Part B drug reimbursement rates were reduced but drug administration rates were increased.[129] Congress and CMS continue to study this issue.

84. Under the MMA, drug manufacturers were required to begin submitting quarterly average sale price ("ASP") data to CMS beginning April 30, 2004.[130] CMS would certainly be able to determine the "spread" on every Medicare Part B drug using these ASPs, although Dr. Hartman continues to assess liability throughout 2004 and

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[125] Hartman Deposition, pp. 879–894, 914–919, and Hartman Deposition Ex. 38, 39, 41.

[126] "However, given the wide range of drugs used in different amounts at different frequencies by different types of physicians in different geographic areas of the country, we would have to survey virtually all physicians in order to get a statistically valid estimate of acquisition costs. Because that would have been burdensome and unfeasible, the Administration therefore determined that it would rely instead of the average wholesale price." See Letter from Donna Shalala to Tom Bliley, Chairman, Commerce Committee, House of Representatives, May 31, 2000, HHC001-0359–62 ("Shalala Letter to Bliley, 2000") at HHC001-0359.

[127] Letter from the Deputy Director, Medicare Contract Management, to Medicare Fiscal Intermediaries and Carriers regarding Pricing for Medicare-Covered Drugs, September 14, 2000, AWP041-0943–AWP041-0946 ("DeParle Letter to Carriers, 2000"), at AWP041-0945. A version of the letter addressed to Congress was reproduced in a publication for Medicare Part B providers in Maine, Massachusetts, New Hampshire, and Vermont by the National Heritage Insurance Company of Hingham, Massachusetts; see Health Care Financing Administration, *Medicare B Resource*, National Heritage Insurance Company, October/November 2000, pp. 17–18, accessible at http://www.medicarenhic.com/news/provider_news/ne_mbr_archive/MedB_HR.pdf ("2000 NHIC Part B Newsletter").

[128] CMS, Competitive Acquisition Program Interim Final Rule (CMS-1325-IFC), June 27, 2003; Letter from Glenn M. Hackbarth, Chairman of MedPAC, to Thomas Scully, Administrator of CMS, October 4, 2002, p. 5.

[129] Johnson, Kjel, "Medicare Reimbursement will Affect Specialty Payouts; MMA Pays Less for Drugs, but More for Administering Them," *Managed Healthcare Executive*, July 1, 2004.

[130] 69 Fed. Reg. 17935 (April 6, 2004).

later. CMS makes the ASPs publicly available, so private payors would also be able to observe these "spreads."

85. Health plan deponents in this matter have directly contradicted Plaintiffs' assumption that payors base reimbursement rates on expectations regarding either acquisition costs or "spreads,"[131] and plans indicated they would not change reimbursement methods if they had more information about the relationship between acquisition cost and AWP.[132] For this reason, Dr. Hartman's expectations theory is simply not credible.

D. Competition is expected to generate variation in price concessions and "move market share," which are not fraudulent

86. Plaintiffs assume that large variations in price concessions (and "spreads") are fraudulent and that efforts by manufacturers to "move market share" are suspicious and motivated by a desire to deceive payors. These assumptions reflect fundamental misunderstandings of the nature of competition.[133] In a perversion of economic principles, these assumptions imply that the harder manufacturers compete with one another, the more likely they are to be found "liable" by Dr. Hartman because price competition causes spreads to increase.[134]

1. Competition generates price concessions, which vary by market conditions and the characteristics of the buyer

87. When several products can be used to treat the same underlying condition, buyers can choose among therapies based on the clinical profile of the drug and its price.

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[131] See section III.C.1.

[132] Spahn Deposition (Anthem BCBS), pp. 93–95; Mulrey Deposition (BCBSMA), pp. 65–73, 129–130; Hailey Deposition (Coventry), pp. 151–152;. Some payors confirmed a similar policy for self-administered drugs; see Deposition of William Fleming (Vice President of pharmacy and clinical integration, Humana), January 11, 2005 ("Fleming Deposition"), p. 18–19, 41–42; Deposition of James Messinger (Vice President of Managed Care, ULLICO), October 22, 2004 ("Messinger Deposition"), pp. 20, 64–65.

[133] For a discussion of the nature of pricing and competition in the pharmaceutical industry, see Congressional Budget Office ("CBO"), *How Increased Competition from Generic Drugs has Affected Prices and Returns in the Pharmaceutical Industry*, July 1998 ("1998 CBO Report").

[134] I discuss movements in benchmark prices in sections V and VI.

Naturally, when more than one drug is effective for a condition, price may be one of the product's characteristics that influences the buying patterns of customers (physicians).[135, 136]

88. In this environment, price concessions are a natural outgrowth of competition. A customer can either expressly negotiate for a lower price by threatening to move his or her business to the rival drug or simply do so when offered a lower price. Customers who behave in this way will extract price concessions from manufacturers of competing drugs.

89. Note, however, that not all patients or physicians may find the drugs to be good substitutes. Some physicians or patients have brand loyalty to a particular drug (for example, they care a great deal about a particular side effect). Since some loyal customers would not switch to the competitor's drug when offered a lower price, they often pay higher prices. The result of these differing tastes and ability to substitute across drugs means we would see a variety of discounts in the market.

90. Variation in discounts is also generated by differences across physicians in terms of the administrative costs resulting from such factors as expedited purchase and delivery requirements or placement of large orders. Variation in discounts also arises from differences in the cost to the manufacturer of *not* serving a particular customer at a particular time, for example, when a rival gains more market share or a plant does not operate at capacity. The process by which manufacturers use discounting to charge different prices to different customers is an important element of price competition.[137]

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[135] See Hartman Liability Report, Attachment F: p. 7 (Smithkline Kytril): "I am requesting a 4.5% increase for all forms of Kytril…using weight based dosing in which the average does should be approximately .7mg Kytril would maintain a price advantage. Kytril IV currently does not have a price advantage compared to Anzemet, however based on Kytril's more favourable safety profile and well established efficacy in preventing chemotherapy induced nausea and vomiting, a higher price for a better product is justified."

[136] I discuss pharmaceutical price concessions more fully in Bell, Gregory K. and Scott Morton, Fiona, Tutorial Submission of the Track One Defendants, "An Orientation to the Acquisition of and Reimbursement for Prescription Drugs," December 3, 2004, section 11.F.

[137] 1998 CBO Report, pp. 23–24.

2. Variation in price concessions causes variation in spreads

91. A benchmark price applies to all customers and changes slowly, while price concessions typically vary over time and across customers. Therefore, the difference between the two, or the spread, must vary. The spread varies across customers, because each customer is able to negotiate a different discount from the manufacturer. The spread varies across drugs, because each drug faces a different level of competition. The spread varies as new technologies are introduced and competition intensifies over the product lifecycle due to entry of therapeutic and generic competitors, new indications for existing drugs, and other factors.

3. Price concessions are normally confidential

92. It is common in many industries for negotiated price concessions to remain confidential, especially when discounts are individually negotiated with buyers. In competition between pharmaceutical products—such as branded therapeutic substitutes—price concessions are likely to occur only if kept confidential.[138] Even health insurance companies generally attempt to maintain the confidentiality of the prices and discounts they negotiate with providers,[139] and the lowest prices reported to the government for the Medicaid program are confidential.[140] Because the transactions of any two buyers often differ in one or more ways and some buyers may not be entitled to the same price terms, their prices would not be the same; thus, public disclosure of discounts may lead to confusion and misunderstandings.

4. Competition is expected to "move market share"

93. It is a fundamental principle in economics that customers "move" market share in response to financial incentives such as lower prices; this is normal economic behavior. More than that, it is crucial to reducing healthcare costs. Imagine what would happen if a manufacturer raised its price and did not lose sales. If that

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[138] Berndt Report, ¶ 166.

[139] For example, Independence Blue Cross considers its reimbursement rates to be propriety trade secrets; see Owens Deposition (Independence BC), pp. 81–83.

[140] The "best price" and average manufacturer price ("AMP") are kept confidential by CMS.

manufacturer were economically rational, it would raise price again and again. The prospect of losing sales (and market share) as prices exceed customers' willingness to pay limits price levels and keeps healthcare costs from being any higher than they otherwise would be. Similarly, when a manufacturer lowers price and gains sales, this is standard price competition.

5. However, Plaintiffs' theory treats vigorous competition as fraudulent

94. Although competition is expected to involve price concessions—which may be quite large—and movements in market share, Plaintiffs nonetheless assume that this normal economic behavior is fraudulent. Plaintiffs assume any action that generates large "spreads," whether due to vigorous price competition or to benchmark price movement, to be fraudulent.

95. Plaintiffs allege that because drug discounts and rebates are paid to providers and do not directly accrue to end payors and patients, they generate inappropriate profits and cause end payors and patients to overpay for drugs.[141] However, allowing intermediaries in the pharmaceutical distribution chain to retain some of the savings associated with price concessions is important in stimulating price competition.[142]

96. As Professor Berndt has stated, for self-administered drugs, payors have allowed providers to have margins on drugs in order to encourage the use of generic drugs.[143] Professor Berndt confirmed that "one widely understood reason third-party payors have long been willing to allow pharmacies to enjoy considerable 'spread' on their generic drugs is that whenever a generic version of a drug is dispensed instead of its brand version, the third-party payor saves a substantial

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[141] Third Amended Complaint, ¶¶ 3, 177–178, 183, 187–194.

[142] Danzon, Patricia, Gail Wilensky, and Kathleen Means, "Alternative Strategies for Medicare Payment—Part B and Beyond," *American Journal of Managed Care*, Vol. 11, No. 3, March 2005, pp. 173–180 at 175. For example, as the FTC notes that the financial incentive of being able to retain part of any cost-reducing effort is an important incentive that drives the PBM to seek lower purchase prices; see FTC Letter to California Assemblyman, 2004, p. 2.

[143] See, for example, Owens Deposition (Independence BC), pp. 182–183.

amount of money."[144] The same principle may apply to physician-administered drugs.[145] More broadly, this example illustrates the principle that allowing some of the savings to remain with a party in the distribution chain can be a purposeful choice on the part of payors to achieve an objective. In a later section, I explain how public and private payors are not only aware of the spread but make use of it to achieve their objectives.

97. When manufacturers or others in the distribution chain compete for a physician's business for generic or branded PADs, they typically offer price concessions. Allowing dispensers to capture some of the benefit of lower acquisition cost creates an incentive for them to be price-sensitive, which ultimately leads manufacturers to compete by reducing prices. A similar incentive is created for any intermediaries in the physician-administered drug distribution chain, such as specialty pharmacies. Ultimately, the final payor benefits from lower costs in the supply chain, and this is why the payor designs reimbursement schemes to include incentives for other parties to seek price concessions.

98. Note also that allowing providers to retain some of the savings from price concessions is more likely to create downward pressure on future reimbursement rates—whether through negotiations with private payors or in public policymaking for Medicare—than if providers received none of the savings from negotiating larger price concessions from manufacturers.

E. No reasonable payor would expect uniform price concessions or "spreads"

1. Payors acknowledge that "spreads" vary across drugs, across buyers, and after therapeutic competition

99. As I discuss above, publicly available reports have documented that "spreads" vary across drugs, and it has also been acknowledged by health plan deponents in this

[144] Berndt Report, ¶ 52.

[145] Payors who reimburse for PADs under a pharmacy benefit program may provide these types of incentives to physicians.

matter[146] and by Medicare policymakers.[147] Payors have also acknowledged the variation in acquisition costs of different buyers[148] and the variation in price concessions that results from therapeutic and generic competition. For these reasons alone, no reasonable payor would expect providers to obtain uniform price concessions or spreads across different drugs.

2. Many payors are aware of variation in "spreads" across specific drugs from their experiences with, and available information about, SADs and PADs

100. As I discuss later, many private payors became involved in drug purchasing from manufacturers through vertical integration into such operations as specialty pharmacies, staff model HMOs, mail order pharmacies, and PBMs.[149] These experiences provided private payors with plentiful information about "spreads" on SADs and PADs.

101. The Congress, the CMS, and the OIG were aware of the variation in "spreads" across specific drugs from their studies of SADs and PADs under the Medicaid program. I do not believe it to be credible to assume they would have forgotten this lesson when turning their attention to the Medicare Part B program.

3. Medicare's repeated studies of acquisition costs would be unnecessary if "spreads" were predictable

102. In its role as a large public payor under the Medicare program, the government is interested in maintaining adequate participation by providers while monitoring the cost of the program. For this reason, Medicare policymakers have routinely studied market participants and the functioning of the industry, including the costs of providers and Medicare Part B reimbursements. Of course, if Medicare policymakers believed there to be a predictable relationship between ASP and

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[146] See section III.A, III.C.

[147] 1992 OIG Report.

[148] See, for example, 1992 OIG Report, Appendix III; Cannon Deposition (IHC Health Plans), pp. 26, 57–58.

[149] See section IV.B.1.

AWP, there would be no need to expend substantial efforts to repeatedly study acquisition costs and price concessions.[150]

4. No reasonable purchaser would expect the same range of discounts for every product for all time

103. While Plaintiffs view the growth in the difference between acquisition costs and reimbursement rates as a purposeful attempt by manufacturers to increase the "spread" above "market expectations," it is unreasonable to expect a market system with many participants to remain static for decades—with or without fraud. Prices and margins would generally be expected to change, for example, due to changes in the competitive landscape (such as consolidation of firms in the industry, entry of new firms, or new products), changes in regulation, or the evolution of operating procedures.

104. In particular, there have been several developments in the pharmaceutical industry that have slowly altered the observed "spread" over the class period. For example, consolidation in the wholesale industry led to economies of scale,[151] so that wholesalers no longer need a 25 percent margin to cover their costs. The development of formularies by PBMs and HMOs intensified price competition among manufacturers to get placement on a formulary. As part of formulary implementation, insurers may send information to physicians about the formulary or use "counter-detailing" representatives, which again intensified price competition as this enabled the insurers to become more adept at moving prescriptions between therapeutic substitutes.[152, 153]

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[150] Dr. Hartman has acknowledged these efforts by payors to inform themselves. See Hartman Declaration of Dec. 16, 2004, fn. 13.

[151] IMS Health, *Pharma Pricing USA: A Comprehensive Review of Pharmaceutical Pricing in the Mid-1990s*, 1995, pp. 103–105.

[152] See, for example, Dietert, Stephanie, "Pharmaceutical Plans Strive to Improve Prescription Benefits," *San Antonio Business Journal*, Vol. 10, No. 36, September 20, 1996.

[153] Information technology allowed for formularies and drug tiers to be applied at the individual patient level and changed with ease. Additionally, adoption of information technology by pharmacies and insurance companies allowed for adding or dropping of pharmacies from an insurer's network easily and inexpensively, which improved an insurer's negotiating position vis-à-vis the pharmacy.